

05-19-03

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PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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**TRANSMITTAL  
FORM**

(to be used for all correspondence after initial filing)

Application Number	09/942,435
Filing Date	August 29, 2001
First Named Inventor	John R. SCHVETTER
Group Art Unit	1654
Examiner Name	M. Audet
Attorney Docket Number	342312003401

Total Number of Pages in This Submission

8 + 32  
References**ENCLOSURES (check all that apply)**

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input checked="" type="checkbox"/> Information Disclosure Statement (3 pages)<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Response to Missing Parts/ Incomplete Application<br><input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Assignment Papers (for an Application)<br><input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____ | <input type="checkbox"/> After Allowance Communication to Group<br><input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences<br><input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input checked="" type="checkbox"/> Other Enclosure(s) (please identify below)<br>1. Form PTO-1449 + copy (4 pages)<br>2. 32 References<br>3. Return postcard |
|---|---|---|

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**Firm  
or  
Individual NameMORRISON & FOERSTER LLP  
Kimberly A. Bolin - 44,546

25226

PATENT TRADEMARK OFFICE

Signature

Date

May 15, 2003

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV332779078US, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 5-15-03

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PATENT  
Docket No. 342312003401

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

John R. SCHWIER and Jerry TAYLOR

Serial No.: 09/942,435

Filing Date: August 29, 2001

For: PROCESSES FOR MAKING  
PHARMACEUTICAL ORAL ECB  
FORMULATIONS AND  
COMPOSITIONS

Examiner: M. Audet

Group Art Unit: 1654

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 AND § 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

Applicants bring to the attention of the Examiner the following co-pending applications:

- Application number 09/763,114 by Borromeo et al., filed February 16, 2001,
- Application number 09/763,559 by Moser et al., filed February 21, 2001,
- Application number 09/868,279 by Rodriguez et al., filed June 15, 2001
- Application number 09/943,901 by Jamison et al., filed August 30, 2001,
- Application number 09/868,347 by Rodriguez et al., filed September 24, 2001.
- Application number 10/087,088 by Burkhardt et al., filed February 27, 2002, and
- Application number 10/378,004 by Burkhardt et al., filed February 27, 2002.

This Supplemental Information Disclosure Statement is submitted:

- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 342312003401. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 15, 2003

Respectfully submitted,

By: \_\_\_\_\_

Kimberly A. Bolin  
Registration No. 44,546

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 342312003401

Application Number 09/942,435

Applicant

John R. SCHWIER and Jerry TAYLOR

Filing Date August 29, 2001

Group Art Unit 2,003

Mailing Date May 15, 2003

**COPY**

## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	10/31/2002	2002-0160942	Larew et al.			
	2.	10/31/2002	2002-0161176	Dalder et al.			
	3.	03/20/2003	2003-0054981	Milton et al.			
	4.	04/13/1993	5,202,309	Schwartz et al.			
	5.	11/12/1996	5,573,936	Kreuzman et al.			
	6.	04/08/1997	5,618,787	Jamison et al.			
	7.	05/13/1997	5,629,289	Rodriguez			
	8.	05/13/1997	5,629,290	LaGrandeur et al.			
	9.	07/08/1997	5,646,111	Borromeo et al.			
	10.	07/29/1997	5,652,213	Jamison et al.			
	11.	12/02/1997	5,693,611	Henle et al.			
	12.	07/28/1998	5,786,325	Borromeo et al.			
	13.	03/28/2000	6,043,341	Udodong et al.			
	14.	07/10/2001	6,258,821	Stogniew et al.			
	15.	11/27/2001	6,323,176	Jamison et al.			
	16.	05/07/2002	6,384,013	Burkhardt et al.			
	17.	01/14/2003	6,506,726	Dobbins et al.			

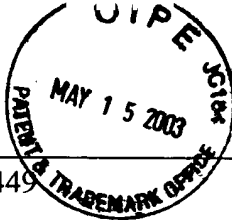
## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO	
	18.	12/08/1991	CA 2,043,762	Canada				
	19.	03/30/1994	EP 0 589 074	Europe				
	20.	11/27/1996	EP 0 744 405	Europe				
	21.	02/05/1997	EP 0 757 058	Europe				
	22.	07/28/1999	EP 0 931 834	Europe				

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

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Docket Number 342312003401

Application Number 09/942,416

Applicant

John R. SCHWIER and Jerry T. ...

Filing Date August 29, 2001

Group Art Unit 1692

Mailing Date May 15, 2003

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	23.	10/28/1991	JP 03 240727	Japan			Abstract Only	
	24.	10/19/1993	JP 05 271097	Japan			Abstract Only	
	25.	06/21/1994	JP 06 172205	Japan			Abstract Only	
	26.	11/10/1994	WO 94/25048	WIPO				
	27.	08/28/1997	WO 97/30695	WIPO				

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	28.	Avis, K. E. (1990). "Parenteral Preparations" Chapter 84 <i>In Remington Pharmaceutical Sciences</i> . 18th edition, Mack Publishing Company pg. 1545-1569.
	29.	Longer, M. A. and Robinson, J. R. (1990). "Transdermal Systems" in Chapter 91 <i>In Remington Pharmaceutical Sciences</i> . 18th edition, Mack Publishing Company. pg. 1690-1693.
	30.	Nema, S. et al. (1997). "Excipients and Their Use in Injectable Products," <i>PDA Journal of Pharm. Science and Tech.</i> 51(4):166-171.
	31.	Sclarra, J. J. and Cutie, A. J. (1990). "Aerosols" Chapter 92 <i>In Remington Pharmaceutical Sciences</i> . 18th edition, Mack Publishing Company. pg. 1694-1712.
	32.	Turco, S. J. (1990). "Intravenous Admixtures," Chapter 85 <i>In Remington Pharmaceutical Sciences</i> . 18th edition, Mack Publishing Company. pg. 1570-1580.

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